ABSTRACT

The methods and reagents described in this invention are used to analyze circulating tumor cells, clusters, fragments, and debris. Analysis is performed with a number of platforms, including flow cytometry and the CellSpotter® fluorescent microscopy imaging system. Analyzing damaged cells has shown to be important. However, there are two sources of damage: *in vivo* and *in vitro*. Damage *in vivo* occurs by apoptosis, necrosis, or immune response. Damage *in vitro* occurs during sample acquisition, handling, transport, processing, or analysis. It is therefore desirable to confine, reduce, eliminate, or at least qualify *in vitro* damage to prevent it from interfering in analysis. Described herein are methods to diagnose, monitor, and screen disease based on circulating rare cells, including malignancy as determined by CTC, clusters, fragments, and debris. Also provided are kits for assaying biological specimens using these methods.